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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOSEPH R. BYRUM and THOMAS J. LA ROSA

Appeal 2008-1235[1]
Application 09/199,129
Technology Center 1600

Decided: September 22, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and
ERIC GRIMES, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 4-12, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Appellants waived their request for Oral hearing (*see* Paper received September 3, 2008).

INTRODUCTION

The claims are directed to a transformed plant (claims 4-7) and a method for determining the level or pattern of protein expression in a plant cell or tissue (claims 8-12). Claims 4 and 8-10 are illustrative:

4. A transformed plant having a nucleic acid molecule which comprises:

(a) an exogenous promoter region which functions in a plant cell to cause the production of an mRNA molecule;

(b) a structural nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof; and

(c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

8. A method for determining a level or pattern in a plant cell or plant tissue of a protein in a plant comprising:

(a) incubating, under conditions permitting nucleic acid hybridization, a marker nucleic acid molecule, said marker nucleic acid molecule selected from the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid molecule having the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 or complement thereof, with a complementary nucleic acid molecule obtained from said plant cell or plant tissue, wherein nucleic acid hybridization between said marker nucleic acid molecule and said complementary nucleic

acid molecule obtained from said plant cell or plant tissue permits the detection of an mRNA for said protein;

(b) permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue; and

(c) detecting the level or pattern of said complementary nucleic acid, wherein the detection of said complementary nucleic acid is predictive of the level or pattern of said protein.

9. The method of claim 8, wherein said level or pattern is detected by *in situ* hybridization.

10. The method of claim 8, wherein said level or pattern is detected by tissue printing.

The Examiner does not rely on prior art to support the rejections of record.

The rejections as presented by the Examiner are as follows:

Claims 4-12 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.

We affirm.

PROCEDURAL HISTORY

This is the second appeal of the subject matter of this Application. Appellants withdrew their first appeal (Appeal No. 2003-2151) by filing a Request for Continued Examination under 37 C.F.R. § 1.114 on January 26, 2005.

CLAIM INTERPRETATION

Claim 4:

Claim 4 is drawn to a transformed plant having a nucleic acid molecule. The nucleic acid molecule of claim 4 comprises the following three parts:

1. an exogenous promoter region that functions in a plant cell to cause the production of an mRNA molecule;

2. a structural nucleic acid molecule; and

3. a 3' non-translated sequence that functions in the plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of the mRNA molecule.

According to claim 4, the structural nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and a complement thereof.

According to Appellants' Specification, "[a]gents of the present invention include nucleic acid molecules and more specifically EST nucleic acid molecules" (Spec. 19: 12-13). SEQ ID NO: 1 is one of 5,521 sequences disclosed in Appellants' Specification (*see, e.g.,* Spec. 11:14-16). The 5,521 nucleic acid molecules, including SEQ ID NO: 1, were isolated from a

cDNA library designated SOYMON001 which was prepared from the leaves of V4 stage plants of the soybean cultivar Asgrow 3244 (Spec. 85: 9-11).

Claim 8:

Claim 8 is drawn to a method for determining a level or pattern of protein expression in a plant cell or plant tissue. The claimed method comprises the following three steps:

(a) incubating[2] a marker nucleic acid molecule[3] with a complementary nucleic acid molecule obtained from a plant cell or tissue;

(b) permitting hybridization between the marker nucleic acid molecule and the complementary nucleic acid molecule; and

(c) detecting the level or pattern of the complementary nucleic acid.

According to claim 8, nucleic acid hybridization between the marker nucleic acid molecule and the complementary nucleic acid molecule permits the detection of an mRNA for the protein, which is predictive of the level or pattern of the protein expressed by the mRNA.

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[2] Claim 8 requires that the incubation step be performed under conditions that permit nucleic acid hybridization.

[3] Claim 8 requires that the marker nucleic acid molecule is selected from the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid molecule having the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 or complement thereof.

DISCUSSION

Claims 4-12 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.[4] According to the Examiner

> [T]here is no disclosed phenotype associated with the claimed transformed plant comprising SEQ ID NO: 1 or complement thereof, nor is there . . . any specific protein described wherein SEQ ID NO: 1 or its complement can be used to determine the level or pattern of expression of said protein in a plant.

(Ans. 5-6.) In addition, the Examiner finds that Appellants' Specification fails to "disclose a utility specific for a nucleic acid comprising SEQ ID NO: 1 or a specific utility or activity for a protein or fragment encoded by a nucleic acid encoding SEQ ID NO: 1 . . . [or] any full length gene which could be isolated using SEQ ID NO: 1" (Ans.[5] 5). At best, the Examiner finds that the utilities disclosed in Appellants' Specification are generic and "generally applicable to any nucleic acid and/or protein" (Ans. 6).

In response, Appellants assert that "the claimed transgenic plants and methods provide clear and immediate benefits, for example, use to follow a

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[4] The Examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for non-enablement was presented simply as a corollary of the finding of lack of utility (*see* Ans. 9). In addition, Appellants rely on their arguments to the rejection under 35 U.S.C. § 101 to rebut the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

[5] All references to the Examiner's Answer (Ans.) refer to the Supplemental Examiner's Answer mailed July 24, 2007.

plant through a breeding program . . ., and to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule" (App. Br.[6] 8). Appellants also assert that the claimed methods are useful in detecting the nucleic acid sequence of SEQ ID NO: 1 (App. Br. 11).

Appellants provide separate arguments for the following groups of claims: (I) claims 4-7; (II) claims 8, 11, and 12; (III) claim 9; and (IV) claim 10. Accordingly, we limit our discussion to claims 4 and 8-10. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 4:

While Appellants' Specification discloses the sequence for the EST having SEQ ID NO: 1, Appellants do not identify and we do not find any further characterization of this nucleic acid molecule. For example, it is unclear what, if any, protein would be encoded by the full length transcript corresponding to this EST. Appellants assert, however, that "transformed plants having, *inter alia*, a structural nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof, have utility independent of whether a function is known for the nucleic acid sequence" (App. Br. 9).

Specifically, Appellants assert that their Specification discloses the use of the nucleic acid sequence as a marker (App. Br. 9, *citing* Spec. 48:22 - 49:5). According to Appellants' Specification, "soybean ESTs" can be used "in marker-assisted breeding programs" (Spec. 18:18-19). In this

[6] All references to Appellants' Brief (App. Br.) refer to the Supplemental Appeal Brief received April 13, 2007.

regard, Appellants assert that their Specification discloses the use of the claimed transgenic plants "in breeding programs to produce plants having genes of interest. *See, e.g.,* Specification at page 18, lines 18-19"[7] (App. Br. 9). According to Appellants, the use of "the claimed transformed plants in a breeding program allows the breeder to readily track the transformed plant through the program by identifying progeny plants containing the nucleic acid molecule" (App. Br. 10). We are not persuaded.

As the Examiner points out, while the nucleic acid of SEQ ID NO: 1 may be used as a marker in a breeding program, such a use is neither specific nor substantial because such a use is generic in each of the "5522 [sic] nucleic acid molecules, fragments thereof, and complements thereof, as disclosed in the specification as filed" (Ans. 13). We agree. Here, as in *In re Fisher*, 421 F.3d 1365, 1374 (Fed. Cir. 2005), the asserted uses are not "specific." Any EST transcribed from any gene in the soybean genome has the potential to perform any one of the alleged uses. Nothing about Appellants' alleged uses set SEQ ID NO: 1, or a plant transformed with a construct comprising SEQ ID NO: 1, apart from the other 5,520 ESTs disclosed in Appellants' Specification or from any EST derived from any organism. Accordingly, we conclude, as did the court in *Fisher*, that Appellants have only disclosed general uses for their claimed transformed plant, not specific ones that satisfy § 101. *Cf. id.*

We are also not persuaded by Appellants' assertion that the claimed plants "provide a particularly appropriate and demonstrably useful starting

[7] We recognize that Appellants also direct attention to "page 56, line 15 through page 75, line 10," which discloses the methodology utilized in transforming plants (App. Br. 9).

point for example, to screen for compounds with herbicidal activity" (App. Br. 12). Appellants do not disclose a relationship between SEQ ID NO: 1 and herbicidal activity. Accordingly, we are not persuaded by Appellants' unsupported conjecture.

For the foregoing reasons, we affirm the rejection of claim 4 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility. Claims 5-7 fall together with claim 4.

Claim 8:

According to Appellants "[u]ses for the claimed methods include detecting the presence or absence or level of expression of the sequence in a sample" (App. Br. 10). This information, however, is meaningless as Appellants have failed to identify any function for the EST having SEQ ID NO: 1. Stated differently, because the claimed EST has no disclosed function, knowing whether a nucleic acid molecule capable of hybridizing to this EST is present, absent, or expressed at a particular level in a plant fails to convey any useful information to a person of ordinary skill in the art. Accordingly, we disagree with Appellants' assertion that "[t]he claimed methods using the nucleic acid molecules are particularly useful, for example, to detect the level in a plant cell or tissue of an mRNA corresponding to SEQ ID NO: 1" (App. Br. 11).

We are also not persuaded by Appellants' assertion that SEQ ID NO: 1 can be used "to detect target genes for producing herbicide tolerant plants" (*id.*). As discussed above, there is no disclosed relationship between SEQ

ID NO: 1, or any of the other 5,520 ESTs disclosed in Appellants' Specification, and herbicidal activity.

For all of the foregoing reasons, we affirm the rejection of claim 8 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility. Claims 11 and 12 fall together with claim 8.

Claim 9:

Claim 9 depends from and further limits the method of claim 8 to require that the level or pattern of complementary nucleic acid obtained from a plant cell or tissue is detected by *in situ* hybridization.

According to Appellants "[*i*]*n situ* hybridization can be used in a number of uses, for example to determine the spatial population or the steady-state levels of RNA accumulation in a tissue . . . to localize specific RNA sequences in cells, which is useful for gene mapping, following chromosomes in hybrid lines or detecting chromosomes with translocations, transversions, or deletions" (App. Br. 12-13). We are not persuaded.

As discussed above, because the EST having SEQ ID NO: 1 has no disclosed function, knowing whether a nucleic acid molecule capable of hybridizing to this EST is present, absent, or expressed at a particular level in a plant fails to convey any useful information to a person of ordinary skill in the art. Further, there is no evidence on this record that SEQ ID NO: 1 would be useful in detecting chromosomes with translocations, transversions, or deletions. Lastly, Appellants disclose nothing with regard to the use of SEQ ID NO: 1 to map genes and follow chromosomes in hybrid lines that would set SEQ ID NO: 1 apart from the other 5,520 ESTs

disclosed by Appellants. Accordingly, we are not persuaded by Appellants' assertions with regard to the general uses of the claimed method.

For the foregoing reasons, we affirm the rejection of claim 9 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility.

Claim 10:

Claim 10 depends from and further limits the method of claim 8 to require that the level or pattern of complementary nucleic acid obtained from a plant cell or tissue is detected by tissue printing.

Appellants assert that "[t]issue printing provides a convenient method to simultaneously screen on a single membrane many tissue sections from different plants or different developmental stages" (App. Br. 14). According to Appellants "[t]he Specification discloses that tissue printing can be used for the histochemical localization of various plant enzymes and nucleic acids" (*id.*). While all of this may be true, Appellants have failed to disclose why tissue printing a nucleic acid that hybridizes to the EST having SEQ ID NO: 1 would be relevant to a person of ordinary skill in the art, when there is no disclosed function or activity for a nucleic acid that hybridizes to a nucleic acid having SEQ ID NO: 1.

Accordingly, for the reasons set forth above, we affirm the rejection of claim 10 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility.

CONCLUSION

In summary, we affirm the rejections of record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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